K131816

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510(k) SUMMARY

JUL 2 3 2013

SUBMITTER:	Sorin Group Deutschland GmbH 25, Lindberghstrasse D-80939 Munich, Germany	
CONTACT PERSON:	Renate Göbert Phone: + 49 (0)89 323-153 Fax: + 49 (0)89 32301333	
DATE PREPARED:	June 7, 2013	
DEVICETRADE NAME:	Sorin CONNECT	
COMMON NAME:	Data Management System	
CLASSIFICATION NAME:	Display, Cathode-ray Tube, Medical	
PREDICATE DEVICE:	IntelliVue Clinical Information Portfolio	K100272
	TLink Data Mangement System	K113214

DEVICE DESCRIPTION:

The Sorin CONNECT is aiming to capture, display and store numerical or other perfusion related information entered by the user or captured from Stockert/Sorin Heart Lung Machine and from any compatible external device via a serial cable connection to the HLM interface.

The capture of the data is performed automatically from the HLM via a serial cable communication or via RFID while simultaneously allowing for simple, manual user inputs

The Sorin CONNECT Data Management System includes a hardware unit (the Personal Computer, hereinafter referred to as Datapad II, and the RFID card/reader hereinafter identified as Heartlink) and the software only product. The Sorin CONNECT software can be embedded into Datapad II (Online version hereinafter identified as

Connect recorder) or available also on a server computer (server version hereinafter identified as Connect Manager).

The Datapad II with embedded Connect Recorder allows for collection of all data that occur during an operation in order to generate a complete case record; its database store data in trend, event, calculation and it is possible to display on the monitor tabular trends or to view measurement trend graphs, with different measurements combined in each graph, to help the perfusionist in identify changes in the patient's physiological condition.

The Connect Manager is a central database application in which all case records are stored and processed; in this case it is possible to consolidate data from different Connect Recorders on one central server computer. The application stores and manages data for documentation, reporting, analysis and export after the clinical case has been done: data are stored in a specific database and it is possible to display on the server workstation tabular trends, measurement trend graphs as well as statistical analysis and document them on a printer.

The two different Sorin CONNECT applications have access to their own, independent database and data transfer among the databases takes place using either an USB memory stick or a network (Ethernet) connection:

- HLM32.DBS is the database on the server computer. This database contains all case records that are already closed.

- ONLINE32.DBS is the database on each of the online computers. This database contains the current case record(s) data.

The Sorin CONNECT, through actuators, software and control mechanisms, performs the data collection, storage and management as requested by the operator through the user interface. Operating modes include automatic collection of data and manual insertion of data via keyboard

The supported medical devices for Sorin CONNECT are the Stöckert/Sorin Heart-lung machines SC (K982014), S3 (950990), S5 (K071318) and C5 (K093882).

INDICATIONS FOR USE:

Sorin CONNECT is a modularly structured program package that is exclusively used with Sorin/Stöckert heart lung machines. The system allows detailed recording of perfusion data during cardiopulmonary bypass as well as the processing and evaluation of this data. The data may be recorded automatically or entered manually.

TECHNOLOGICAL CHARACTERISTICS:

Sorin makes the claim of substantial equivalence to cited predicates based on intended use, indications for use, technological characteristics, and operational characteristics.

Sorin CONNECT and the predicates are software only products intended to be installed on a PC or on a server. They have a client server architecture and are compliant with the up to date Micrsosoft® Operating System and databases.

The related software supports a standard hospital LAN interface and Sorin device interface for connection to the compatible measuring devices.

Sorin Group Deutschland GmbH believes that the Sorin CONNECT is substantially equivalent to the IntelliVue family of Patient Data Management solutions, to TLink DMS and to other currently marketed data management devices, that any differences are minor, and raise no new issues of safety and effectiveness.

The summary of equivalences regarding general features and performance characteristics of the Sorin CONNECT and the predicate devices is presented below

Parameters	Sorin CONNECT	INTELLIVUE	TLink DMS	Equivalence
Intended use	Sorin CONNECT is a modularly structured program package that is used together with Sorin heart lung machines. The system allows detailed recording of systemic perfusion data during cardio-surgical interventions; as well as the processing and evaluation of these data afterwards. The recording of the data is performed automatically or via RFID while simultaneously allowing for simple, manual user inputs.	The INTELLIVUE is intended for use in the data collection, storage, and management with independent bedside devices and ancillary systems that are connected either directly or through networks. This device is indicate for use by the health care providers whenever there is a need for generation of a patient record and computation drug usage	The TLink DMS is an electronic clinical record keeping and reporting system indicated for use in collecting, displaying, storing and managing data from external medical devices. The system facilitates the creation of electronic patient records and enables post-procedural case reviews. Data and records can be viewed in local workstations or transferred to a central computer or hospital network for storage and post-case analysis/reporting	Equivalent to TLink as both system are tailored for use in both OR and afterwards by perfusionists Equivalent to INTELLIVUE but limited to data management of cardiac surgery intervention (IntelliVue can be used also for bedside data management) and not intended for the scope of computation drug usage but only for generation of patient record

Modules division	Connect Manager (central database application – based on both server and/or PC-) Connect recorder (online application – PC based-)	IntelliVue XDS application (central database application – based on both server and/or PC-) IntelliVue monitors (online application – PC based-)	TLink Data management system (central database application –based on both server and/or PC-) TLink Data management system (On line application based on a touch screen PC)	Equivalent to both INTELLIVUE and TLink : all system have a SW application which can be loaded on a PC or on a server and an online application loaded on the monitor where data are collected (which is actually a PC as well)
Parameters	Sorin CONNECT	INTELLIVUE	TLink DMS	Equivalence
User interface	Touch screen without additional input devices (Connect Recorder) Standard keyboard and mouse of commercial PC (Connect Manager)	Touch screen; additional input devices like mouse, remote control or trackball can be used (IntelliVue monitors) Standard keyboard and mouse of commercial PC (XDS application)	Touch screen computer Standard keyboard and mouse of commercial PC (TLink DMS)	Equivalent to both INTELLIVUE and TLink
Data source	Manually, Automatically captured by compatible measuring devices, RFID card reader, calculations	Manually, Automatically captured by compatible measuring devices, RFID card reader, calculations	Manually, Automatically captured by compatible measuring devices, bar code scanner, calculations	Equivalent to INTELLIVUE. Only difference with TLink is that ; it is not using a RFID card reader but a bar code reader
Data management	The operator can at any moment overrule the data entry in any mode and manually enter or modify each single parameter and save the modified data	The operator can at any moment overrule the data entry in any mode and manually enter or modify each single parameter and save the modified data	The operator can at any moment overrule the data entry in any mode and manually enter or modify each single parameter and save the modified data	identical to both INTELLIVUE and TLink

Data storage	Relational database PC embedded (Connect recorder) Relational database PC and/or central database server embedded (Connect manager)	Relational database PC embedded (IntelliVue monitors) Relational database PC and/or central database server embedded (XDS application)	Relational database PC embedded (TLink DMS embedded into the touch screen computer) Relational database PC and/or central database server embedded (TLINK DMS	Equivalent to both INTELLIVUE and TLink
Parameters	Sorin CONNECT	INTELLIVUE	TLink DMS	Equivalence
Data transfer/ backup	Data can be transferred to/from: connect manager connect recorder via: - portable storage medium - network connection - WLAN connection	Data can be transferred to/from: IntelliVue monitors to XDS application: - portable storage medium - network connection - WLAN connection - Telemetry	Data can be transferred via: - portable storage medium - network connection - WLAN connection	Equivalent to TLink. Only difference with INTELLIVUE is that ; it allows transfer of data also using telemetry (not possible in Connect and Tlink)
Data Output	Numerical, graphical, statistical,	Numerical, graphical, waves, statistical,	Numerical, graphical, statistical,	Equivalent to TLink. Only difference with INTELLIVUE is that ; it allows data output also in form of wave pulse (not possible in Connect and Tlink)
Fundamental scientific technology	Microsoft.NET framework together with WLAN module	Microsoft.NET framework together with WLAN module	Microsoft.NET framework together with WLAN module	Equivalent to to INTELLIVUE and TLink
Availability	Availability as a standalone SW embedded into a PC or into a LAN Network	Availability as a standalone SW embedded into a PC or into a LAN Network	Availability as a standalone SW embedded into a PC or into a LAN Network	Identical to INTELLIVUE and TLink

Materials	Hardware: PC Firmware: Microsoft Windows XP	Hardware: PC Firmware: Microsoft Windows XP	Hardware: PC Firmware: Microsoft Windows (version Not available)	Equivalent to INTELLIVUE and TLink
Sterilization /Shelf Life	Not sterile	Not sterile	Not sterile	Identical to INTELLIVUE and TLINK
Biocompatibility	No blood contacting parts	No blood contacting parts	No blood contacting parts	Identical to INTELLIVUE and TLINK
EMC (emissions)	Group 1 Class A (CISPR 11)	Group 1 Class A (CISPR 11)	Data not available	Identical to INTELLIVUE
Parameters	Sorin CONNECT	INTELLIVUE	TLink DMS	Equivalence
Electromagnetic compatibility and electrical safety	UL 60601-1 (IEC 60601-1, A1, A2) and IEC 60601-1-2 testing	UL 60601-1 (IEC 60601-1, A1, A2) and IEC 60601-1-2 testing	Data not available	Identical to INTELLIVUE

IN VITRO TEST RESULTS:

Testing supplied in the 510(k) premarket notification for the Sorin CONNECT includes electrical testing, electromagnetic compatibility testing, and performance testing that demonstrate compliance with performance specifications.

The purpose of the performance testing was to ensure the performance of the device by verifying and stressing the PC server and client specifications and simulating various scenarios of real customer deployment in the hospital, The conducted performance tests have confirmed performances of the Sorin CONNECT software together with the compatible measuring devices and the local infrastructures under conditions simulating real environment of use.

The results of the study showed the device characteristics between Sorin CONNECT and IntelliVue were comparable.

The list of tests performed to fulfill compliance with the nonclinical tests is presented below with the relevant standard followed

TEST	STANDARD
Vibration test	ASTM D999, version 6, Aug 1st, 2008
Drop test	ASTM D5276 version 9, March 1st, 2009
Software	IEC 62304 version 1, May1st, 2006
Off the shelf Software	FDA Guidance for the compliance on Off-the-Shelf software used in medical devices, September 9, 1999
Cybersecurity	FDA Guidance for networked Medical devices containing Off-the-Shelf software January 14, 2005
Usability	IEC 62366: 2007
Health information technology	ANSI HL 7 V2.5-2003
Electromagnetic compatibility	IEC 60601-1-2, version 3, March 1st, 2007
Electrical safety	IEC 60601-1:2005, 3rd ed.
Risk management	ISO14971, version 3, July 1st, 2009
Wireless technology	FDA guidance for radio frequency Wireless technology in medical devices, Jan 3, 2007

CONCLUSIONS:

The results of *in vitro* studies demonstrate that the Sorin CONNECT is substantially equivalent to the predicate device in terms of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 23, 2013

Sorin Group Deutschland GmbH
c/o Mr. Olaf Tiechert
Responsible Third Party Official
TUV SUD America, Inc.
1775 Old Highway 8 NW
New Brighton, MN 55112

Re: K131816
Trade/Device Name: Sorin "CONNECT Data Management System"
Regulatory Number: 21 CFR 870.2450
Regulation Name: Display, Cathode-Ray tube, Medical
Regulatory Class: II (two)
Product Code: 74 DXJ
Dated: July 2, 2013
Received: July 11, 2013

Dear Mr. Tiechert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K131816

Indications for Use

Device Name: Sorin CONNECT Data Management System

Indications for Use:

Sorin CONNECT is a modularly structured program package that is exclusively used with Sorin/Stöckert heart lung machines. The system allows detailed recording of perfusion data during cardiopulmonary bypass as well as the processing and evaluation of this data. The data may be recorded automatically or entered manually.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.07.23 12:49:36 -04'00'